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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,022	11/26/2001	Holger G. Gassner	07039-171002	1634

26191 7590 03/23/2005

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EXAMINER
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JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/995,022	<b>Applicant(s)</b> GASSNER ET AL.	
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1614	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

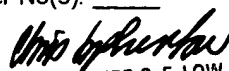
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 23 and 32-46.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☒ Other: See Continuation Sheet.

  
 CHRISTOPHER S. F. LOW  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1600

Continuation of 13. Other: Regarding arguments directed to Sanders et al., Applicants assert that separate administration of botulinum toxin, a local anesthetic and a local vasoconstrictive agent does not anticipate a composition of matter that includes a solution of botulinum toxin and either a local anesthetic agent or a local vasoconstrictive agent or both. The examiner maintains that since all three agents are administered sequentially into the nares of a dog, that the nares is the container into which the composition of matter is deposited, then the composition of matter is therefore anticipated by Sanders et al. Regarding Adams et al., applicant argues that proper 103 analysis requires that the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition and whether the prior art would also have revealed that in so making, those of ordinary skill would have had a reasonable expectation of success. Adams et al. teach that saxitoxin, like botulinum toxin, is employed to induce nerve blocks in laboratory animals (column 1, lines 42-47). Botulinum toxin is employed for nerve blockade. Further, it is revealed that the toxin, when administered in combination with a local anesthetic manifests in profoundly prolonged longevity of action with the combinations of the toxin with local anesthetics so that the toxin may be administered well below the toxic level (column 1, lines 48-55). The motivation to combine the two agents is the surprisingly prolonged activity. The local anesthetic may contain well known vasoconstrictors such as epinephrine, norepinephrine, phenylephrine, and levonordefrin (column 7, line 49 to column 8, line 35). Motivation to substitute botulinum toxin for the saxitoxin of Adams et al. would be 1. Both are employed for nerve blockade and 2, both can be toxic when administered in a dose that is too high. Adams et al. teach that by combining the local anesthetic with the neurotoxin, the effective amount to be administered can be less than the amount administered without the local anesthetic, thus effectively lowering the effective dose, prolonging activity as recited above and avoiding toxicity.